

Applicant : Peters et al.
Appl. No. : 10/595,601
Examiner : Luther G. Behringer
Docket No. : 13634.4011

REMARKS

The Office Action dated September 4, 2009 has been carefully considered. Claim 39 have been amended.

Claims 39—48 have been rejected as unpatentable over Kapp et al. Patent No. 4,256,094 in view of Anonymous, "Use of Heart Valve Sounds as Input to Cardiac Assist Devices", in view of Lekholm Patent No. 4,763,646. Applicants have carefully reviewed Kapp, Anonymous and Lekholm and submit that the cited references fail to teach or suggest each of the limitations of the claims and, thus, fail to establish a *prima facie* case of obviousness.

The claimed invention is directed to an apparatus for controlling the pulsations of a heart assist device. Specifically, the claim reads in pertinent part:

In an apparatus for controlling the pulsations of a heart assist device to alternate between compression of a blood vessel and withdrawal of compression of the blood vessel in a timed relationship with the pulsing of a patient's heart...

As such, the claims are cast as Jepson type claims such that the preamble of these claims must be taken into account as a meaningful element of the claims. The effect of Jepson type claims is explained in some detail in *Rowe v. Dror*, 112 F.3d 473, 479 (Fed. Cir. 1997) and in *Manual of Patent Examining Procedure*, Section 608.01m. As stated in the latter, the Jepson form of claim:

“is to be considered a combination claim. The preamble of this form of claim is considered to positively and clearly include all the elements or steps recited therein as part of the claimed combination.”

Thus, the rejection based on Kapp is not applicable as Kapp does not teach or suggest an apparatus for controlling the pulsations of a heart assist device.

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Although Applicants disagree with the examiner assertion that Kapp discloses a "heart assist device," even if Kapp's pump 26 and cuff 12 could be considered to meet the heart assist device limitations of claim 39, Kapp fails to teach or suggest "an apparatus for controlling the pulsations of a heart assist device to alternate between compression of a blood vessel and withdrawal of compression of the blood vessel in a timed relationship with the pulsing of a patient's heart." In contrast, Kapp is directed to a device and the control of a device for reducing the arterial blood pressure to a selected body site such as the head or brain by occluding or partially occluding the artery using an inflatable cuff. An apparatus to control such a device is fundamentally different from the claimed apparatus to control the pulsation of a heart assist device as there is no timed relationship with the patient's pulsing heart, nor is there the alternation between compression and withdrawal of compression of the patient's vessel. Rather there is constant compression of the vessel at varying degrees to maintain a desired pressure downstream of the cuff 12.

Simply stated, there is absolutely no disclosure in Kapp involving pulsatile heart assist of a blood vessel nor is there any disclosure in Kapp of any device for controlling a pulsatile heart assist device which is coupled to the blood vessel.

Even if one were to accept the examiner's assertion that "Kapp discloses an apparatus for controlling the pulsation of a heart assist device," Anonymous and Lekholm do not cure the deficiency of Kapp of failing to disclose positioning within the fluid of a heart assist device, a microphone adapted to detect heart sounds in the blood vessel as acknowledged by the examiner.

The prior art cited by the examiner taken alone or combination in the manner suggested by the examiner does not disclose the idea of putting the microphone in contact with a fluid

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Appl. No. : 10/595,601
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Docket No. : 13634.4011

transmitting pressure between a pump and a cuff, nor do they suggest the advantages that flow from such placement of the microphone. The advantages of placing the microphone in the fluid between the pump and the cuff include:

1. The microphone is isolated from the surrounding blood and tissue thereby avoiding any adverse reaction in either the blood or tissue on the one hand and the microphone on the other;
2. There is no additional surgery required to place the microphone in the patient (as there is, for instance, in Lekholm);
3. The fluid serves to transmit the sound clearly to the microphone (rather in the manner of a stethoscope). As the cuff is in contact with the blood vessel containing blood from the heart there is a fluid filled path from the heart right to the microphone;
4. The pump, cuff and conduit between them shield the microphone from external sounds that could interfere with the correct detection of the heart sounds; and
5. The microphone can be placed a distance from the cuff if required with the advantage that the pump and the microphone may both be placed outside the patient's body.

Not only does the cited art not teach or suggest each of the limitations of the claimed invention, the cited art taken alone or together actually teaches away from the claimed invention and/or the combination of the cited art proposed by the examiner. The examiner relies on Anonymous to meet the limitation of using heart sounds to control a heart assist device. However, Anonymous identifies a major concern about the use of such heart sounds in saying "One justifiable concern is the influence of external (outside the body) sounds and the possibility of a false-positive trigger." According to Anonymous, the problem of accurately detecting hearts

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sounds can be addressed through circuitry regardless of location of the sensor (microphone). As a result, a person skilled in the art would not, in view of Anonymous, think of any special placement of the microphone because Anonymous says that simple filtering through control circuitry is enough. Moreover, in a heart assist device the life of the patient may well be dependent upon the device sensing when to pulsate accurately and reliably over millions of cycles. It is quite possible to pick up many types of spurious "noise" with a microphone. Simple circuitry to filter out such noise is not reliable enough to entrust the life of a patient to. By contrast, in the claimed invention the microphone is placed within fluid between the pump and the cuff and thus can detect heart sounds clearly and substantially without spurious noise and pick up the sounds from the heart with a sound to noise ratio sufficient to insure that control of a heart assist device can be relied upon.

Lekholm describes the use of heart sounds to control a pacemaker. There is no teaching of the use of the type of heart assist device according to the claimed invention combined with the use of heart sounds let alone the use of a microphone receiving signals from a fluid conveying pressure from a pump to a cuff. Lekholm (col 3, lines 47 to 56) suggests that "The sensing of the intra-atrial and intraventricular pressure is then achieved by the connection of a catheter from the transducers in the pacemaker can 12 to the heart 11. The catheter has two tubes or lumens that are typically filled with a fluid that is an efficient transmitter of pressures from inside the heart to the pressure transducers" . Lekholm is thus suggesting the placement of the pressure sensing tubes or lumens within the blood stream in the heart. This raises exactly the problem identified by Anonymous that placement of the sensor in the blood stream leads to the development of blood clots (thrombogenesis). Anonymous, which states, "Unfortunately, even the current state-

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Appl. No. : 10/595,601
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Docket No. : 13634.4011

of-the –art pressure sensors invariably promote thromogenesis after chronic implantation and are unsuitable for long term use," effectively teaches away from a combination with Lekholm as a result.

In addition, Lekholm's placement of the sensing tubes or lumens with the blood stream is quite a different proposal than the placement of the microphone within a fluid of the heart assist device between the heart assist device's pump and cuff. Whether Lekholm places the pressure sensors around the heart as in Fig 3 or within the heart as in Fig 2 there is far more surgery involved for the patient as compared with claimed invention.

Furthermore, the examiner suggests that it would be obvious to substitute the microphone of Anonymous for the pressure sensor of Kapp. Applicants submit that there would be no incentive for anyone skilled in the art to do that. Kapp is seeking to avoid unduly high blood pressure downstream of an occluding cuff. The detection of heart sounds would not provide any kind of signal that would assist in reducing distal vascular blood pressures and, thus, the modification of Kapp by Anonymous would frustrate Kapp for its intended purpose. As a result, there is no incentive for a person skilled in the art to combine Kapp with Anonymous or Anonymous with Lekholm, and even if they did combine the teachings of these references, they would not arrive at a situation in which a sound receiver is positioned in the fluid between a pump and a cuff surrounding a blood vessel.

Claims 39—48 are believed to be patentable. Thus, it is respectfully requested that the rejections based on Kapp, Anonymous and Lekholm be withdrawn.

It is believed that the present application is in condition for allowance and a favorable action is respectfully solicited.

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Appl. No. : 10/595,601
Examiner : Luther G. Behringer
Docket No. : 13634.4011

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 15-0665.

Respectfully submitted,
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/Kenneth S. Roberts/

Dated: December 2, 2009

By: _____
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